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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/716,474	11/20/2003	Takahiro Kikuchi	KAS-195	6873

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EXAMINER	
RIVIERE, HEIDI M	

ART UNIT	PAPER NUMBER
3689	

MAIL DATE	DELIVERY MODE
12/24/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/716,474	KIKUCHI ET AL.	
	Examiner	Art Unit	
	HEIDI RIVIERE	3689	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 October 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *26-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *26-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/20/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed **13 October 2009** have been fully considered but they are not persuasive. Applicant has deleted claims 1-25 and replaced with claims 26-46. Applicant argues that the new claims are novel and patentable because they do not teach or suggest "an information transmission unit connected to the information supervisor device". Motegi teaches that information is transmitted from the analyzer system to a microcomputer. The supervisor being the manufacturer would receive this information via the computer or software or recording medium. Therefore the rejections are not withdrawn.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. **Claims 26-46** are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over **Motegi et al. (US 2002/0076352 A1**) (hereinafter "**Motegi**").

4. **With respect to claims 26 and 38:** (New) A cross-contamination prevention system relating to an automatic analyzer having a reagent pipetting

probe for pipetting a predetermined amount of a reagent into a reaction cuvette and a rinsing mechanism for rinsing said reagent pipetting probe, comprising: (Motegi: Fig. 4; paragraphs 31 – reagent pipetting information)

- an information supervisor device storing reagent cross-contamination information of a combination of an offensive reagent and a defensive reagent to be affected by the offensive reagent; an information transmission unit connected to the information supervisor device through a first communication line and a first automatic analyzer, the information transmission unit transmitting reagent cross-contamination information obtained by a test using the first automatic analyzer to the information supervisor device; and an information receiver unit connected to the information supervisor device through a second communication line and a second automatic analyzer, the information receiver unit receiving the reagent cross-contamination information stored in the information supervisor device from the information supervisor device; (Motegi: paragraph 19 “to make automatic judgement of the combinations of the items involving contamination for preventing the occurrence of errors of determination due to contamination, said recording medium having stored therein an operating program which, in order to prevent the occurrence of errors of determination due to the generation of new contamination by a change of the state of the apparatus, makes judgement on whether contamination is present or not, memorizes its result, compares the result with those of the previous judgments, and when these results differ more

than a certain degree, judges that the state of the apparatus has changed, and indicates it to the user."- paragraphs 32-35 – microcomputer used;)

a. wherein the information supervisor device includes a true or false validating unit to validate whether the reagent cross-contamination information transmitted from the information transmission unit is true or false; and wherein the information supervisor device includes a transmitting mechanism to transmit the reagent cross-contamination information stored in the information supervisor device and judged to be true by the true or false validating unit to the information receiver unit periodically. (Motegi: Figs. 2 and 3 – contaminating test for and system responds with "yes" or "no").

It would be obvious to find that the terms true and false can be substituted for yes no. The message or response conveyed is the same.

Furthermore, the data identifying response is non-functional descriptive data.

When presented with a claim comprising descriptive material, an Examiner must determine whether the claimed nonfunctional descriptive material should be given patentable weight. The Patent and Trademark Office (PTO) must consider all claim limitations when determining patentability of an invention over the prior art. *In re Gulack,* 703 F.2d 1381, 1385, 217 USPQ 401,404 (Fed. Cir. 1983). The PTO may not disregard claim limitations comprised of printed matter. *See Gulack,* 703 F.2d at 1384-85,217 USPQ at 403; *see also Diamond v. Diehr,* 450 U.S. 175, 191,209 USPQ 1, 10 (1981). However, the examiner need not give

patentable weight to descriptive material absent a new and unobvious functional relationship between the descriptive material and the subset. See *In re Lowry,* 32 F.3d 1579, 1583-84, 32 USPQ2d 1031, 1035 (Fed. Cir. 1994); *In re Ngai,* 367 F.3d 1336, 1338, 70 USPQ2d 1862, 1863-64 (Fed. Cir. 2004). Thus, when the prior art describes all the claimed structural and functional relationships between the descriptive material and the subset, but the prior art describes a different descriptive material than the claim, then the descriptive material is nonfunctional and will not be given any patentable weight. That is, such a scenario presents no new and unobvious functional relationship between the descriptive material and the subset.

The Examiner asserts that the data identifying response adds little, if anything, to the claimed acts or steps and thus do no serve as limitations on the claims to distinguish over the prior art. MPEP 2106IV b 1(b) indicates that "nonfunctional descriptive material" is material "that cannot exhibit any functional interrelationship with the way the steps are performed". Any differences related merely to the meaning and information conveyed through data, which does not explicitly alter or impact the steps is non-functional descriptive data. The subjective interpretation of the data does not patentably distinguish the claimed invention.

2. **With respect to claim 27:** (New) A cross-contamination prevention system according to claim 26, wherein the reagent cross-contamination information contains at least one of information for identifying an offensive reagent, information for identifying a defensive reagent, information regarding a

level of influence of the cross- contamination, information regarding a contamination place, information regarding a detergent type, or information regarding a detergent volume. (motegi: paragraphs 77-83 - system has information of "item giving influence; item A"; "item receiving influence; item B"; Amount of detergent; amount of reagent used in item A)

3. **With respect to claims 28 and 40:** (New) A cross-contamination prevention system according to claim 26, wherein the second automatic analyzer connected to the information receiver unit includes an analyzer operating unit to change an operation sequence of the second automatic analyzer on the basis of the reagent cross-contamination information received by the information receiver unit. (Motegi: Fig. 4 – more than one analyzers; paragraphs 57-65 – "Automatic analyzers are usually provided with an expedient for inhibiting the occurrence of contamination, such as a cleaner system. Therefore, if some trouble or other arises in the analyzer to cause a change in the state of the contamination preventing mechanism, there is produced a corresponding change in the influence of contamination."; "The interval of determination is also previously registered in the case of an analyzer which can be always loaded with the sample for making judgement on the presence of absence of contamination, allowing to conduct determination at the registered interval during the ordinary analysis of the sample. In the case of an analyzer incapable of always carrying the sample, determination is conducted at arbitrary intervals in the ordinary sample analysis by using a specific sample rack or other suitable means"))

4. **With respect to claims 29 and 41:** (New) A cross-contamination prevention system according to claim 28, wherein the second automatic analyzer connected to the information receiver unit includes a display unit to display the reagent cross-contamination information received by the information receiver unit, the display unit displaying an instruction to instruct the analyzer operating unit whether or not the operation sequence of the second automatic analyzer is to be changed. (Motegi: Figs. 4, 6 and 7- display screen of contamination information; paragraphs 32-35 – microcomputer used)

5. **With respect to claims 30 and 42:** (New) A cross-contamination prevention system according to claim 29, wherein the second automatic analyzer connected to the information receiver unit includes a validation unit to validate an ability of suppressing cross-contamination of the second automatic analyzer, the display unit displaying the ability of suppressing cross-contamination of the second automatic analyzer. (Motegi: Figs. 2-5 – contaminating test for and system responds with “yes” or “no”)

6. **With respect to claims 31 and 43:** (New) A cross-contamination prevention system according to claim 26, wherein the information supervisor device determines a charge in exchange for the reagent cross-contamination information transmitted from the information transmission unit based on whether the reagent cross-contamination information is judged to be true or false by the true or false validating unit. (Motegi: Figs. 2 and 3 – contaminating test for and system responds with “yes” or “no”)

7. **With respect to claims 32 and 44:** (New) A cross-contamination prevention system according to claim 26, wherein each of the first and second automatic analyzers is an automatic analyzer comprising: a memory to store reagent cross-contamination information; and an analyzer operating unit that receives instruction for changing an operation sequence of the automatic analyzer to prevent the occurrence of the cross- contamination on the basis of the reagent cross-contamination information stored in the memory, and carries out the operation sequence to prevent the occurrence of the cross-contamination in accordance with the received instruction. (Motegi: Figs. 4, 6 and 7- display screen of contamination information; paragraphs 19, 32-35 – microcomputer used)

8. **With respect to claim 33:** (New) A cross-contamination prevention system according to claim 26, wherein the second automatic analyzer connected to the information receiver unit is configured to automatically take in the cross-contamination information and (Motegi: Fig. 4 – more than one analyzers)

- change an operation sequence of the analyzer as required. (Motegi: paragraphs 57-65 – "Automatic analyzers are usually provided with an expedient for inhibiting the occurrence of contamination, such as a cleaner system. Therefore, if some trouble or other arises in the analyzer to cause a change in the state of the contamination preventing mechanism, there is produced a corresponding change in the influence of contamination."; "The interval of determination is also previously

registered in the case of an analyzer which can be always loaded with the sample for making judgement on the presence of absence of contamination, allowing to conduct determination at the registered interval during the ordinary analysis of the sample. In the case of an analyzer incapable of always carrying the sample, determination is conducted at arbitrary intervals in the ordinary sample analysis by using a specific sample rack or other suitable means")

9. **With respect to claims 34:** (New) A cross-contamination prevention system according to claim 33, wherein the second automatic analyzer connected to the information receiver unit is configured to display the cross-contamination information having been automatically taken in, to ask an operator of the second automatic analyzer whether or not the operation sequence of the second automatic analyzer is to be changed, to register a result of confirmation made by the operator, and to change the operation sequence of the second automatic analyzer in accordance with the registration result. (Motegi: Figs. 4, 6 and 7-display screen of contamination information; paragraphs 32-35 – microcomputer used)

10. **With respect to claim 35:** (New) A cross-contamination prevention system according to claim 34, wherein the second automatic analyzer connected to the information receiver unit is configured to validate its own ability of suppressing cross-contamination, and to determine whether or not the operation sequence of the second automatic analyzer is to be changed, based on a combination of the

validated ability of suppressing cross-contamination and the cross-contamination information having been automatically taken in. (Motegi: paragraphs 57-65 – "when investigating the influence of contamination, it is checked whether a similar investigation has been conducted with the same combination of items as shown in FIG. 3 (step S3-1), and the result of judgement is compared with that in the previous investigation (step S3-2). [0060] In case a combination of items which has been judged to have no contamination before is now judged as having contamination, an alarm informing of the occurrence of trouble in the contamination preventing mechanism is issued (step S3-3)"; "Automatic analyzers are usually provided with an expedient for inhibiting the occurrence of contamination, such as a cleaner system. Therefore, if some trouble or other arises in the analyzer to cause a change in the state of the contamination preventing mechanism, there is produced a corresponding change in the influence of contamination."; "The interval of determination is also previously registered in the case of an analyzer which can be always loaded with the sample for making judgement on the presence of absence of contamination, allowing to conduct determination at the registered interval during the ordinary analysis of the sample. In the case of an analyzer incapable of always carrying the sample, determination is conducted at arbitrary intervals in the ordinary sample analysis by using a specific sample rack or other suitable means")

11. **With respect to claims 36 and 45:** (New) A cross-contamination prevention system according to claim 26, wherein each of the first and second automatic analyzers is an automatic analyzer which is configured to read a reagent barcode

label of each of a plurality of reagent bottles for identification of reagents, to register the reagents, and to confirm washing ability of the automatic analyzer by testing. (motegi: Fig. 4; paragraph 30-35- automatic analyzer; paragraph 40-42 – vessel cleaning mechanism)

12. **With respect to claims 37 and 46:** (New) A cross-contamination prevention system according to claim 36, wherein each of the first and second automatic analyzers is an automatic analyzer which is configured to: compare a reagent manufacturer name and test information contained in the reagent barcode label with information of combinations causing cross-contamination stored as reagent cross-contamination information in the memory to check for presence or absence of a combination causing cross-contamination; (motegi; paragraph 15 - analyzer memorizes information and compares

- if there is presence of a combination causing cross-contamination, issue an alarm indicating the presence, evaluate the washing ability of the automatic analyzer and display the combination causing cross-contamination for which washing is recommended, and prompt an operator to select whether to carry out registration of cross-contamination prevention or not; and if the operator selects to carryout registration of cross-contamination prevention, register cross-contamination prevention information. (Motegi: paragraphs 57-65 – "when investigating the influence of contamination, it is checked whether a similar investigation has been conducted with the same combination of items as shown in FIG. 3 (step S3-1), and the result of judgement is compared with that in the previous

investigation (step S3-2). [0060] In case a combination of items which has been judged to have no contamination before is now judged as having contamination, an alarm informing of the occurrence of trouble in the contamination preventing mechanism is issued (step S3-3)"; "Automatic analyzers are usually provided with an expedient for inhibiting the occurrence of contamination, such as a cleaner system. Therefore, if some trouble or other arises in the analyzer to cause a change in the state of the contamination preventing mechanism, there is produced a corresponding change in the influence of contamination."; "The interval of determination is also previously registered in the case of an analyzer which can be always loaded with the sample for making judgement on the presence of absence of contamination, allowing to conduct determination at the registered interval during the ordinary analysis of the sample. In the case of an analyzer incapable of always carrying the sample, determination is conducted at arbitrary intervals in the ordinary sample analysis by using a specific sample rack or other suitable means")

CONCLUSION

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Heidi Riviere whose telephone number is 571-270-1831. The examiner can normally be reached on Monday-Friday 9:00am-5:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janice Mooneyham can be reached on 571-272-6805. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. R./
Examiner, Art Unit 3689

/Dennis Ruhl/
Primary Examiner, Art Unit 3689

CONCLUSION

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Examiner, Art Unit 3689